IN THE UNITED STATES DISTRICT COURT	
FOR THE SOUTHERN DISTRICT OF NEW YOR	RK

WILLIAM GURNEY; and ZACHARY JORDAN,

Plaintiffs,

ν.

PFIZER INC.,

Defendant.

Civil Action No.: 08 CV 3875

JUDGE: THOMAS P. GRIESA

COMPLAINT AND

DEMAND FOR JURY TRIAL

#### COMPLAINT

Plaintiffs by way of Complaint against the Defendants, upon information and belief allege as follows:

### PARTIES-PLAINTIFFS

- 1. Plaintiff, WILLIAM GURNEY, is a citizen of the Commonwealth of Massachusetts, residing therein at 1160 Summerset Avenue, Taunton, MA, 02780. Plaintiff, WILLIAM GURNEY, was given prescriptions and samples of Viagra (Sildenafil Citrate), which he ingested from approximately March of 2001 until February of 2006, as prescribed by his doctor for erectile dysfunction. Plaintiff, WILLIAM GURNEY, suffered vision loss in his left eye in October of 2005 and was subsequently diagnosed with Non Arteritic Ischemic Optic Neuropathy ("NAION").
- 2. Plaintiff, ZACHARY JORDAN, is a citizen of the State of Arizona, residing therein at 7706 West Marco Polo Road, Glendale, Arizona 85308. Plaintiff, ZACHARY JORDAN, was given prescriptions and samples of Viagra (Sildenafil Citrate), which he ingested from approximately May 30, 2001 until October 20, 2003, as prescribed by his doctor for erectile dysfunction. Plaintiff, ZACHARY JORDAN, suffered vision loss in his right eye on

Case 1:08-cv-03835-TPG Document 1 Filed 04/23/2008 Page 2 of 17 approximately April 28, 2003 and was diagnosed with Ischemic Optic Neuropathy (hereinafter referred to as "ION").

#### PARTIES- DEFENDANT

- 3. The Defendant, Pfizer (hereinafter referred to as "Pfizer" or "Defendant"), is a Delaware corporation, which has its principal place of business located at 235 East 42<sup>nd</sup> Street, New York, New York 10017.
- 4. At all times material hereto, the Defendant, Pfizer, was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Viagra.
- 5. Defendant is, and was at all relevant times, duly authorized to conduct business in the State of New York.
- 6. Defendant, either directly or through its agents, servants, and employees, regularly solicits and transacts business within the State of New York.
- 7. Defendant, at all relevant times, has sold and distributed Viagra in the State of New York for use in the treatment of male impotence/erectile dysfunction.
- 8. Defendant derives substantial revenue from goods used or consumed in the State of New York.
- 9. Defendant expected, or should have expected, that its actions could or would have consequences within the State of New York.

### GENERAL BACKGROUND AND OVERVIEW OF CLAIMS

10. This is an action for damages suffered by the Plaintiffs as a direct and proximate result of the Defendant's negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling,

Case 1:08-cv-03835-TPG Document 1 Filed 04/23/2008 Page 3 of 17 and/or sale of the pharmaceutical product known as Viagra (Sildenafil Nitrate) (hereinafter referred to as "Viagra" or "the subject product").

- 11. At all times material hereto, Defendant designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold Viagra for the treatment of male erectile dysfunction/impotence.
- 12. As a result of the defective nature of Viagra, those persons who were prescribed and ingested Viagra, including Plaintiffs, have suffered and continue to suffer severe and permanent injuries, including Non-Arteritic Ischemic Optic Neuropathy (NAION), Arteritic Ischemic Optic Neuropathy (AION), Posterior Ischemic Optic Neuropathy (PION), Ischemic Optic Neuropathy ("ION"), Branch Retinal Artery Occlusion (BRAO), Central Retinal Artery Occlusion (CRAO), and any other condition resulting in sudden vision loss due to blocked blood flow to the optic nerve.
- 13. The above mentioned conditions can lead to decreased vision or blindness in one or both eyes.
- 14. Defendant knew of the significant risk of vision loss caused by ingestion of Viagra, but, Defendant did not adequately and sufficiently warn consumers, including Plaintiffs, or the medical community, of such risks.
- 15. Defendant failed to conduct adequate post-marketing surveillance of Viagra after it began marketing, advertising, distributing and selling the product.
- 16. Consumers, including Plaintiffs, who have used Viagra for treatment of erectile dysfunction/impotence, have several alternative safer products available to treat this condition.
- 17. As a result of Defendant's actions, Plaintiffs and their prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that the Plaintiffs had been exposed to the risks identified in this complaint, and that those risks were the direct and proximate result of Defendant's acts, omissions, and misrepresentations.

- 18. As a direct result, Plaintiffs were prescribed and ingested Viagra and have been permanently and severely injured. Plaintiffs require and will require ongoing medical care and treatment.
- 19. Consequently, Plaintiffs seek actual and punitive damages for their injuries resulting from their ingestion of Viagra, which has caused and will continue to cause the Plaintiffs to suffer pain, mental anguish and other injuries, as well as to incur significant expenses.

#### **JURISDICTION**

20. This Court has jurisdiction pursuant to 28 United States Code §1332, as complete diversity exists between Plaintiffs and the Defendant. Plaintiff, ZACHARY JORDAN, is a citizen of the State of Arizona. Plaintiff, WILLIAM H. GURNEY, is a citizen of the Commonwealth of Massachusetts. The Defendant, PFIZER, is incorporated and has its principal place of business in the State of New York. The amount in controversy exceeds seventy five thousand dollars (\$75,000.00), exclusive of interest and costs.

#### SUBSTANTIVE ALLEGATIONS

- 21. Viagra is the brand name of Sildenafil Citrate, one of a class of drugs called "phosphodiesterase inhibitors," which is used to prevent the destruction of cyclic guanosine monophosphate (hereinafter referred to as "cGMP"), which effects the amount of blood that the blood vessels deliver and remove from the penis. Sildenafil provides benefits to those with erectile dysfunction/impotence problems.
- 22. Viagra is a Phosphodiesterase inhibitor, which is designed to prevent the destruction of the cGMP and allow smooth muscle relaxation and inflow of blood into the penis, helping with the erection of the penis upon stimulation.

- 23. On March 27, 1998, defendant Pfizer obtained approval from the United States Food and Drug Administration (hereinafter "FDA") for the use of Viagra as a prescription drug for the treatment of erectile dysfunction/impotence.
- 24. On July 8, 2005, the FDA released a Statement titled "FDA Updates Labeling for Viagra, Cialis and Levitra for Rare Post-Marketing Reports of Eye Problems" (annexed hereto as Exhibit 1). The labeling was updated to reflect a small number of post-marketing reports of sudden vision loss where blood flow was blocked to the optic nerve in consumers using Viagra.
- 25. On July 8, 2005, the FDA also released an "Alert for Healthcare Professionals" (annexed hereto as Exhibit 2). This alert provided data as of May 18, 2005, which indicated a total of Forty-Three cases of Ischemic Optic Neuropathy (ION) among patients using Viagra, Cialis, or Levitra, that have been reported to the FDA's Adverse Event Reporting System.

  Thirty-Eight of those cases were identified in association with Viagra.
- 26. On July 8, 2005, defendant Pfizer finally acknowledged the increased risk of Sudden Vision Loss associated with Viagra and strengthened the label by adding a warning under the Precautions section, in the Information to Patients subsection (annexed hereto as Exhibit 3), which stated:

Physicians should advise patients to stop use of all PDE5 inhibitors, including VIAGRA, and seek medical attention in the event of sudden loss of vision in one or both eyes. Such an event may be a sign of non-arteritic anterior ischemic optic neuropathy (NAION), a cause of decreased vision including permanent loss of vision, that has been reported rarely post-marketing in temporal association with the use of all PDE5 inhibitors. It is not possible to determine whether these events are related directly to the use of PDE5 inhibitors or to other factors. Physicians should also discuss with patients the increased risk of NAION in individuals who have already experienced NAION in one eye, including whether such individuals could be adversely affected by use of vasodilators, such as PDE5 inhibitors.

27. Defendant Pfizer knew or should have known that the use of Viagra involved serious health risks, including, but not limited to, NAION, AION, ION, PION, CRAO, BRAO,

Case 1:08-cv-03835-TPG Document 1 Filed 04/23/2008 Page 6 of 17 and any other condition resulting in sudden vision loss due to blocked blood flow to the optic nerve.

- 28. Defendant Pfizer concealed their knowledge of Viagra's unreasonably dangerous risks from the Plaintiffs, other consumers, and the medical communities and continued to manufacture, sell, and promote Viagra without adequately warning of these serious health risks.
- 29. Defendant Pfizer failed to conduct adequate pre-clinical and clinical testing and post-marketing monitoring to adequately determine the safety and health risks of Viagra.
- 30. Defendant Pfizer failed to use due care in designing, testing, and manufacturing Viagra so as to avoid these serious health risks.
- 31. Despite its knowledge, Defendant Pfizer failed to provide adequate training, information or education to physicians and consumers about these serious health risks and about the precautions necessary to avoid these health risks.
- 32. Despite its knowledge, Defendant Pfizer represented to physicians, including the Plaintiffs' prescribing physicians, and to consumers, including the Plaintiffs, that Viagra was safe and effective for use.
- 33. Defendant Pfizer knowingly withheld and/or misrepresented information regarding these serious health risks of Viagra, which it was required to submit to the FDA.
- 34. Had Defendant Pfizer properly disclosed the risks associated with using Viagra to the Plaintiffs' physicians, the Plaintiffs would have been properly warned and would not have taken the drug.

### EQUITABLE TOLLING OF APPLICABLE STATUES OF LIMITATIONS:

40. The running of any statute of limitations has been tolled by reason of Defendant's fraudulent concealment. Defendant, through its affirmative misrepresentations and omissions,

Case 1:08-cv-03835-TPG Document 1 Filed 04/23/2008 Page 7 of 17 actively concealed from the Plaintiffs and their prescribing physicians; the true risks associated with taking Viagra.

- 41. As a result of Defendant's actions, Plaintiffs, and upon information and belief, their prescribing physicians, were unaware, and could not reasonably know or have learned through reasonable diligence that she had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendant's acts and omissions.
- 42. Furthermore, Defendant is estopped from relying on any statue of limitations because of their fraudulent concealment of the true character, quality and nature of Viagra. Defendant was under a duty to disclose the true character, quality and nature of Viagra because this was non-public information over which the Defendant had and continues to have exclusive control, and because the Defendant knew that this information was not available to the Plaintiffs, medical providers and/or to their facilities. In addition, the Defendant is estopped from relying on any statue of limitations because of their international concealment of these facts.
- 43. The Plaintiffs had no knowledge that the Defendant was engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by the Defendant, the Plaintiffs could not have reasonably discovered the wrongdoing at any time prior. Also, the economics of this fraud should be considered. The Defendant had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting a profitable drug, notwithstanding the known or reasonably known risks. Plaintiffs and medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely on only the Defendant's representations.

### COUNT I Negligence

44. The foregoing paragraphs of this Complaint are realleged and incorporated by

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- 45. Defendant had a duty to consumers, including the Plaintiffs, to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling Viagra.
- 46. Defendant failed to exercise due care under the circumstances, and therefore breached its duty to the Plaintiffs.
- 47. Defendant's negligent acts and omissions, either directly or through its agents, servants, and employees, include, but are not limited to the following:
  - a. Designing, manufacturing, marketing, advertising, distributing, and selling Viagra to consumers, including the Plaintiffs, without an adequate warning of the dangerous risks of Viagra and without proper instructions to avoid harm caused by Viagra;
  - b. Failing to exercise due care when advertising and promoting Viagra; and
  - c. Failing to exercise ordinary care by conducting appropriate post-market testing and surveillance of Viagra.
- 48. Although Defendant knew, or should have known, of Viagra's adverse effects

  Defendant has continued to negligently manufacture, market, advertise, distribute, and sell

  Viagra to consumers, including the Plaintiffs, so as to maximize sale and profits at the expense of public health and safety in knowing, conscious and deliberate disregard of the foreseeable harm caused by the subject product.
- 49. Defendant knew, or should have known, that consumers, including the Plaintiffs, would suffer injuries as a result of Defendant's failure to exercise ordinary care.
- 50. As a direct and proximate result of the Defendant's negligence and other wrongdoing and actions of Defendant described herein, the Plaintiffs have sustained serious and permanent injuries, and will continue to suffer injury, harm, and economic loss.

### COUNT II Strict Liability – Failure to Warn

- 51. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.
- 52. Defendant designed, tested, manufactured, marketed, sold and/or distributed Viagra. As such, it had a duty to warn the using public, including the Plaintiffs, of the health risks associated with using the subject product.
- 53. The subject product was under the exclusive control of Defendant and was unaccompanied by appropriate warnings regarding the health risks associated with its use, including vision loss. The warnings given did not accurately reflect the risk, incidence, symptoms, scope or severity of such injury to the consumer. The promotional activities of Defendant further diluted or minimized the warnings given with the product.
- 54. The subject product was defective and unreasonably dangerous when it left the possession of the Defendant in that it contained warnings insufficient to alert the Plaintiffs to the dangerous risks and reactions associated with it, including, but not limited to vision loss. Even though Defendant knew or should have known of the risks and reactions associated with the subject product, it still failed to provide warnings that accurately reflected the signs, symptoms, incidence, scope, or severity of these risks.
- 55. The Plaintiffs used the subject product for its intended purpose, i.e. for the treatment of male erectile dysfunction/impotence.
- 56. The Plaintiffs could not have discovered any defect in the subject product through the exercise of reasonable care.

- 57. The Plaintiffs would not have used Viagra had Defendant properly disclosed the risks associated with the drug.
- 58. Defendant, as a manufacturer of pharmaceutical drugs, is held to the level of knowledge of an expert in the field, and further, Defendant had knowledge of the dangerous risks and side effects of the subject product.
- 60. The Plaintiffs did not have the same knowledge as Defendant and no adequate warning was communicated to them.
- 61. Defendant had a continuing duty to warn consumers, including the Plaintiffs, of the dangers associated with the subject product. By negligently and/or wantonly failing to adequately warn of the dangers of use of the subject product, Defendant breached its duty.
- 62. Although Defendant knew of the defective nature of the subject product, they continued to design, manufacture, market, and sell it without providing accurate, adequate, and complete warnings concerning its use so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by the subject product.
- 63. As a direct and proximate result of the Defendant's failure to adequately warn or other wrongdoing and actions of Defendant described herein, the Plaintiffs have sustained serious and permanent injuries, and will continue to suffer injury, harm, and economic loss.

## COUNT III Strict Liability – Defective Design

64. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.

- 65. Defendant is the manufacturer, seller, distributor, marketer, and/or supplier of the subject product, which is defective and unreasonably dangerous to consumers.
- 66. The subject product was designed, manufactured, sold, distributed, supplied, marketed, and/or promoted by Defendant, and was expected to reach and did reach consumers, including the Plaintiffs, without substantial change in the condition in which it was manufactured and sold by Defendant.
- 67. The subject product was defective in its design and was unreasonably dangerous in that its foreseeable risks exceeded the benefits associated with its design or formulation.
- 68. Consumers, including the Plaintiffs, who have used Viagra for the treatment of male erectile dysfunction/impotence, have several alternative safer products available to treat this condition.
- 69. Although Defendant actually knew of the defective nature of the subject product, it continued to design, manufacture, market, and sell it so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious and deliberate disregard of the foreseeable harm caused by the subject product.
- 70. As a direct and proximate result of the design defects of the subject product, the Plaintiffs have sustained serious and permanent injuries, and will continue to suffer, injury, harm, and economic loss.

# COUNT IV Breach of Express Warranty

71. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.

- 72. Defendant expressly represented to the Plaintiffs, other consumers and the medical community that Viagra was safe and fit for its intended purposes, of merchantable quality, did not produce any dangerous side effects, and was adequately tested.
- 73. Viagra does not conform to Defendant's express representations because it is defective and unfit for its intended purpose, i.e. it is not safe, has numerous and serious side effects, and causes severe and permanent injuries.
- 74. The subject product was defective and unreasonably dangerous when it left the possession of the Defendant in that it contained warnings insufficient to alert the Plaintiffs to the dangerous risks and reactions associated with it, including, but not limited to vision loss.
- 75. At all relevant times Viagra did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.
- 76. The Plaintiffs, other consumers and the medical community relied upon Defendant's express warranties.
- 77. As a direct and proximate result of Defendant's express warranties of the subject product, the Plaintiffs have sustained serious and permanent injuries, and will continue to suffer, injury, harm, and economic loss.

# COUNT V Breach of Implied Warranty

- 78. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.
- 79. Defendant designed, tested, manufactured, marketed, sold and/or distributed Viagra.

- 80. At all relevant times, Defendant knew of the use for which Viagra was intended and impliedly warranted the product to be safe and fit for such use.
- 81. Defendant was aware that consumers, including the Plaintiffs, would use Viagra for the treatment of male erectile dysfunction/impotence, and knew, or recklessly disregarded, that consumers, including the Plaintiffs, and the medical community relied upon its judgment and sensibility to only sell Viagra if it was safe and fit for its intended use.
- 82. Defendant herein breached its implied warranty to consumers, including the Plaintiffs; Viagra was not safe or fit for its intended use.
- 83. Consumers, including Plaintiff, and the medical community reasonably relied upon Defendant's implied warranty for Viagra.
- 84. Viagra reached the Plaintiffs without substantial change in the condition in which it was manufactured and sold by Defendant.
- 85. As a direct and proximate result of Defendant's implied warranties of the subject product, the Plaintiffs have sustained serious and permanent injuries, and will continue to suffer, injury, harm, and economic loss.

## COUNT VI Common Law Fraud

- 86. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.
- 87. Defendant falsely and fraudulently represented to the medical community, and to the Plaintiffs and the public in general, that Viagra had been tested and found to be safe and effective for the treatment of male erectile dysfunction/impotence.

- 88. Defendant knew, or should have known, that its representations were false yet it willfully, wantonly and recklessly disregarded its obligation to provide truthful representations regarding the safety and risks of Viagra to consumers, including the Plaintiffs, and the medical community.
- 89. Defendant's representations were made with the intent of defrauding and deceiving consumers, including the Plaintiffs, and the medical community, with the intent of encouraging and inducing sales of Viagra.
- 90. Defendant knowingly, consciously, and deliberately placed its financial gain above the rights and safety of the Plaintiffs and other consumers.
- 91. Defendant's fraudulent representations evinced its callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including the Plaintiffs.
- 92. The Plaintiffs were unaware of the falsity of Defendant's representations and reasonably relied upon Defendant's representations, thereby developing ION or NAION with sudden vision loss.
- 93. As a direct and proximate result of Defendant's fraudulent misrepresentation of the subject product, the Plaintiffs have sustained serious and permanent injuries, and will continue to suffer, injury, harm, and economic loss.

### COUNT VII Punitive Damages

- 94. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.
  - 94. Although Defendant knew or recklessly disregarded the fact that the subject

Case 1:08-cv-03835-TPG Document 1 Filed 04/23/2008 Page 15 of 17 product causes debilitating and potentially lethal side effects, Defendant continued to market the subject product to consumers, including the Plaintiffs, without disclosing these side effects.

- 96. Defendant knew of the subject product's defective nature, as set forth herein, but continued to design, manufacture, market, and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including the Plaintiffs, in conscious and/or negligent disregard of the foreseeable harm caused by the subject product.
- 97. Defendant intentionally concealed or recklessly failed to disclose to the public, including the Plaintiffs, the potentially life-threatening side effects of the subject product to ensure their continued and increased sales. This intentional and/or reckless failure to disclose information deprived the Plaintiffs of the information necessary for them to weigh the true risks of using the subject product against the benefits.
- 98. Defendant's aforementioned conduct was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers such as the Plaintiffs, thereby entitling the Plaintiffs to punitive damages in an amount appropriate to punish Defendant and it from similar conduct in the future.

WHEREFORE, the Plaintiffs demand judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

# COUNT VIII Violation of G.B.L. § 349

- 99. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.
- 100. Defendant's misrepresentations and concealment of material fact constitute unconscionable commercial practices, deception, fraud, false pretenses, misrepresentation, and/or the knowing concealment, suppression or omission of material facts with the intent that

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- 101. Defendant engaged in the deceptive acts and practices alleged herein in order to sell a consumer product, Viagra, to the public, including the Plaintiffs.
- 102. Defendant intentionally concealed facts known to it, as alleged herein, in order to ensure the increased sales of Viagra.
- 103. Defendant's conduct, as alleged herein, was likely to mislead reasonable consumers, such as the Plaintiffs, acting reasonably under the circumstances to believe that Viagra was a safe treatment for male erectile dysfunction/impotence.
- 104. As a direct and proximate result of Defendant's actions, the Plaintiffs have sustained serious and permanent injuries, and will continue to suffer, injury, harm, and economic loss.

WHEREFORE, the Plaintiffs demand judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

#### PRAYER FOR RELIEF

WHEREFORE, the Plaintiffs respectfully pray of this Court and demand of Defendant as follows:

- d. That Plaintiffs be granted and recover actual damages incidental to their purchase and use of Viagra in an amount to be determined at trial;
- e. That Plaintiffs be granted and recover treble and punitive damages;
- f. That Plaintiffs be granted pre-judgment and post-judgment interest;
- g. That the costs of this action be taxed to Defendant;

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- h. That Plaintiffs be granted reasonable attorneys' fees and costs as provided by law; and
- i. For such other and further relief as the Court may deem just and proper.

### JURY TRIAL DEMANDED

The Plaintiffs demand a trial by jury on all issues.

Dated: 4|21|08

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By:

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